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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,804	08/16/2001	Carla M. Mann	AB-047U2	3341

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,804

Applicant(s)

MANN ET AL.

Examiner

Kennedy Schaetzle

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-39 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-19,21-30 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 31-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4 and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Lue et al. (Pat. No. 4,585,005).

Lue et al. disclose a method for stimulating at least one tissue affecting specific anatomical structures of the perineum comprising a stimulator 12 that generates a stimulation pulse in accordance with prescribed stimulation parameters, a lead 13 connected to the stimulator including at least two electrodes (note col. 6, lines 8-13) for delivering the stimulation and implanted adjacent to at least one tissue of the perineum to be stimulated (note col. 6, lines 56-66 and Figs. 1-4). The stimulator 12 is implanted at a location remote from the stimulated tissue, and the lead is subcutaneously tunneled to the stimulator location (see col. 7, lines 15-18).

Regarding claim 4, note again col. 6, lines 56-66.

Regarding claim 31, comments made in the rejection of claim 1 apply here as well.

Regarding claim 33, note col. 6, lines 49-55.

Regarding claims 32, 34 and 35, the examiner considers the nerves shown in Fig. 1 to originate from the sacral nerve roots and incorporate a pudendal nerve or nerve branch of the penis.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tanagho et al. (Pat. No. 4,607,639).

Regarding claim 1, as shown in Fig. 12, Tanagho et al. disclose a method of stimulating tissue affecting specific anatomical structures of the perineum comprising providing a stimulator, providing a lead with at least two electrodes for applying a

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stimulation pulse adjacent thereto, implanting the electrodes adjacent to the at least one tissue of the perineum (note cols. 6 and 7), implanting the stimulator at a location remote from the at least one tissue (note col. 2, lines 12-26). The examiner considers it inherent that if the receiver discussed in col. 2 is to be implanted subcutaneously and the electrodes surgically or percutaneously implanted remote therefrom, then the leads 26, 27, 47 and 48 must be tunneled to the stimulator location.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. in view of Whitehurst et al. (Pat. No. 6,650,943).

Lue et al. do not discuss the use of a sensor and thus do not discuss adjusting stimulation parameters based on a sensed condition. Whitehurst et al., however, disclose a related device that can also be used in the treatment of erectile dysfunction that does include a sensor. Closed loop control of stimulation parameters via the sensor is taught to be advantageous from the standpoint of enhancing the effectiveness of treatment. Those of ordinary skill in the art desiring a more responsive treatment method would have therefore seen the obviousness of incorporating a sensor into the Lue et al. invention. It would also have been considered obvious by those of ordinary skill in the art to utilize the external appliance of Lue et al. to process the sensor signal so as to limit the complexity of the implant itself and not require an implantable processor. The transmission of raw signals from an implant to an external device for analysis and processing is old and well-known in the prior art.

6. Claims 4 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho et al. (Pat. No. 4,607,639) in view of Lue et al. (Pat. No. 4,585,005).

Regarding claim 4, Tanagho et al. do not appear to discuss depositing the electrodes through the skin of the perineum. Tanagho et al., however, do state that the electrodes may be percutaneously implanted. Lue et al. discloses a nerve stimulator with percutaneous implantation of electrodes through the perineum (see the rejection of claim 4 under Lue et al. above). Such an anatomical location is a well-known surgical access point to the nerve structures associated with the pelvic region including not only those associated with the functioning of the penis, but also those associated with control of bladder functioning. To suggest that percutaneous insertion of the electrodes of the Tanagho et al. device be made through the perineum would have therefore been considered a matter of obvious surgical prerogative given that it was known at the time of the invention to percutaneously implant nerve stimulator electrodes in this manner as taught by Lue et al..

Regarding claim 31, note the comments made above with regards to the rejection of claims 1 and 4.

Regarding claim 32 and 35, note the text abridging cols. 6 and 7.

Regarding claim 33, note Fig. 14 and the associated text.

Regarding claim 34, note col. 4, lines 9-18.

7. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho et al. (Pat. No. 4,607,639) in view of Lue et al. (Pat. No. 4,585,005) as applied to claims 4 and 31-35 above, and further in view of Roe et al. (Pat. No. 6,266,557).

Tanagho et al. in view of Lue et al. do not discuss the use of a sensor. Roe et al. disclose a related system for controlling bladder evacuation that utilizes a sensor to provide biofeedback signals related to the action of sphincter muscles so as to inform the patient of an impending elimination of bodily waste. Incorporating a sensor with a bodily waste control device permits the patient to take action prior to the evacuation event, thus giving the individual greater control and confidence. Artisans of ordinary skill in the art given the disclosure of Roe et al. would have therefore seen the

advantage of incorporating a sensor in the method defined by Tanagho et al. and Lue et al..

Response to Arguments

8. Applicant's arguments filed June 7, 2004 have been fully considered but they are not persuasive. The addition of the phrase "...to treat patients with incontinence, urgency, frequency, and/or pelvic pain..." to both the preamble and the claim body fails to patentably distinguish over the Lue et al. reference. Such statements are considered by the examiner to be merely statements of intended use. Lacking any specific steps limiting the method to such treatment, the rejection under Lue et al. must remain.

Conclusion


9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaeztle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
August 28, 2004



KENNEDY SCHAEZTLE
PRIMARY EXAMINER